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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/084,491	05/27/98	MOORE	P PF378

022195
HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE MD 20850

HM22/0725

EXAMINER	
SLOBODYANSKY,E	
ART UNIT	**PAPER NUMBER**
1652	17

DATE MAILED: 07/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/084,491	Moore et al.
Examiner	**Group Art Unit**
Elizabeth Slobodyansky	1652

☒ Responsive to communication(s) filed on *Apr 20, 2000* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *21-71, 73, and 74* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *21-71, 73, and 74* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The amendment filed April 20, 2000 canceling claims 17, 19, 72 and 75 and amending claims 21, 57 and 69 has been entered.

The statement regarding the availability of the Biological Deposit signed by Mr. Joseph Kenny is presented on pages 5 and 6 of Remarks.

Upon further consideration and in view of Applicants remarks claims 55 and 56 have been rejoined with claims 21-54, 57-71, 73 and 74.

Claims 21-71, 73 and 74 are pending.

Rejections and/or objections not reiterated from the previous Office action are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The reference JP 10265498 has been considered insofar as the alignment of the sequence presented on page 7 thereof and SEQ ID NO:2 of the instant application. The reference is cited on form PTO-892 attached hereto.

Specification

The specification is objected to because of the following. Figure 2 shows an alignment of t-PALP and human t-PA. SEQ ID NO:2 consisting of 263 amino acids is aligned with residues 191-516 of t-PA. On page 7, lines 9-10, the t-PA sequence is referred to as SEQ ID NO:3. SEQ ID NO:3 has 372 amino acids. Residues 191-516 of t-PA on Figure 2 correspond to residues 1-325 of SEQ ID NO:3. Correction should be made to make Figure 2 consistent with its description.

Claim Rejections - 35 USC § 101

Claims 21, with dependent claim 22-56, claim 57, with dependent claims 58-71, and claims 73-74 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The specification discloses a DNA of SEQ ID NO:1 encoding a protein of 263 amino acids (SEQ ID NO:2). The specification discloses that "SEQ ID NO:2 is about 21.3% identical" to human t-PA sequence shown at Figure 2. As stated above, Figure 2 shows an alignment of residues 191-516 of human t-PA (residues 1-325 of SEQ ID NO:3) and SEQ ID NO:2. Therefore, the overall percent identity with t-PA is much lower. There is no additional data to support putative function. Such data would include a higher homology for the specific domains, such as protease domain, and location of

putative catalytic triad in SEQ ID NO:2, for example. The sequence search performed by PTO shows that SEQ ID NO:2 and SEQ ID NO:3 have no appreciable homology. In fact, the specification does not provide any evidence of an enzymatic activity for the protein encoded by SEQ ID NO:1. Therefore, as disclosed, a protein of SEQ ID NO:2 is an uncharacterized protein. In view of this, the polynucleotide of SEQ ID NO:1 encoding the protein of SEQ ID NO:2 has no specific, substantial and well-established utility.

In their Remarks filed April 20, 2000 Applicants argue that t-PALP is "useful, for example, as hybridization probes" (page 6). However, the use as a hybridization probe is a nonspecific utility that would apply to virtually every member of a general class of DNA. Therefore, it can not be counted as a specific or substantial or well established utility.

Claims 21, with dependent claim 22-56, claim 57, with dependent claims 58-71, and claims 73-74 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

In case Applicants would establish utility for a DNA encoding SEQ ID NO:2, including SEQ ID NO:1, the following rejections will still apply.

Claim Rejections - 35 USC § 112

Claims 73 and 74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules comprising at least 30 and 50 nucleotides, respectively, of residues 630 to 750 of SEQ ID NO:1.

The specification does not contain any disclosure of the function of all DNA sequences that comprise at least 30 or 50 nucleotides of residues 630 to 750 of SEQ ID NO:1. The genus of cDNAs that comprise these above cDNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. One skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 73 and 74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a fragment consisting of at least 30 and 50 nucleotides of residues 630 to 750 of SEQ ID NO:1, respectively, does not reasonably provide enablement for a fragment comprising at least 30 and 50 nucleotides, respectively, of residues 630 to 750 of SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 73 and 74 are drawn to a nucleic acid molecule comprising 30 and 50 nucleotide fragments of SEQ ID NO:1. "An isolated polynucleotide" of claims 73 and 74 is not limited in length. Further, there is no information regarding other nucleotides contained in a claimed polynucleotide comprising 30 or 50 of SEQ ID NO:1. Therefore, claims 73 and 74 encompass countless number of sequences with an unknown function.

Contrary to Applicants arguments (pages 7 and 8 of Remarks filed April 20, 2000), there is no guidance presented as to what is the specific function of the sequences. It is unpredictable what is the function of an encoded polypeptide. Although it is routine in the art to make a nucleotide sequence, it is not routine and it is extremely unpredictable what the structure of a polypeptide encoded by said nucleotide sequence would be and how this polypeptide, once made, could function. Due to the

unpredictable nature of the art, the lack of guidance set forth by the specification regarding a specific function of a polypeptide encoded by a polynucleotide that comprises 30 or 50 nucleotides of SEQ ID NO:1, and a great number of encompassed polynucleotides, it would require undue experimentation for one skilled in the art to find the use for a nucleic acid molecule of claims 73 and 74.

Claims 56 and 71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 56 and 71 are drawn to a composition comprising a polynucleotide and a thrombolytic agent. The Examiner is unable to locate adequate support in the specification for such compositions. Thus there is no indication that a composition comprising a polynucleotide and a thrombolytic agent was within the scope of the invention as conceived by Applicants at the time the application was filed.

Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

Claims 56 and 71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Claims 56 and 71 are drawn to a composition comprising a polynucleotide and a thrombolytic agent. While it is known in the art how to use some compositions comprising a polynucleotide, it is unknown how to use a composition further comprising a thrombolytic agent. The specification does not provide a teaching needed to use said composition.

Claims 54 and 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 54 is drawn to a method for producing a protein by culturing a host cell under conditions suitable to produce a polypeptide.

Claim 74 is dependent from claim 73. Claim 73 is drawn to a polynucleotide comprising at least 30 contiguous nucleotides. Claim 74 is drawn to a polynucleotide of claim 73 further comprising at least 50 contiguous nucleotides. It is unclear whether claim 74 is encompassing one fragment or two separate fragments.

Claim Rejections - 35 USC § 102

Claims 73 and 74 are rejected under 35 U.S.C. 102(a) as being anticipated by Du et al.

Du et al. (accession AC002073, May 12, 1997, form PTO-1449 filed March 8, 1999) teach a sequence comprising at least 50 nucleotides of residues 630-750 of SEQ ID NO:1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner

July 19, 2000